4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0333]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the procedure by which both domestic and foreign bottled water manufacturers that sell bottled water in the United States maintain records of microbiological testing and corrective measures, in addition to existing recordkeeping requirements.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water--21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h) (OMB Control Number 0910-0658)--Extension

The bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are Escherichia coli. The adulteration provision of the bottled water standard (§ 165.110(d)) provides that a finished product that tests positive for E. coli will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require that source water from other than a public water system (PWS) be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are E. coli. Source water found to contain E. coli is not considered water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for E. coli, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain E. coli

will be considered negative for E. coli after five samples collected over a 24-hour period from the same sampling site are tested and found to be E. coli negative.

Description of Respondents: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 129.35(a)(3)(i), § 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08	153
§ 129.80(g), § 129.80(h)	95 (bottlers testing finished product only)	3	285	0.08	23
§ 129.35(a)(3)(i), § 129.80(h)	3 (bottlers conducting secondary testing of source water)	5	15	0.08	1.2
§ 129.35(a)(3)(i), § 129.80(h)	3 (bottlers rectifying contamination)	3	9	.25	2
Total Annual Burden					179

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for E. coli are negligible. We estimate that the labor burden of keeping records of each test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for E. coli when

total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about three times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for E. coli.

We expect that recordkeeping for the followup test for E. coli will also take about 5 minutes per test. As shown in table 1 of this document, we expect that 3 bottlers per year will have to carry out the additional E. coli testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, E. coli testing, and source rectification, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: January 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-01032 Filed 01/17/2013 at 8:45 am; Publication Date: 01/18/2013]